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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| <i>Customer No.:</i> | 23643 | { } |
| <i>Group:</i> | 1651 | |
| <i>Confirmation No.:</i> | 9910 | |
| <i>Application No.:</i> | 10/775,386 | |
| <i>Patent No.:</i> | 7,482,025 | |
| <i>Invention:</i> | Biomaterial Derived from Vertebrate Liver Tissue | |
| <i>Inventor:</i> | Stephen F. Badylak | |
| <i>Filed:</i> | February 10, 2004 | |
| <i>Attorney Docket:</i> | 3220-74469 | |
| <i>Examiner:</i> | Allison M. Ford | |

FILED ELECTRONICALLY:
March 27, 2009

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705(d)

Mail Stop Patent Extension
Director for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

It is respectfully requested that the Office reconsider the Patent Term Adjustment determined in the above-identified U.S. Patent No. 7,482,025, and revise the Patent Term Adjustment to **1082 days**, which is believed to be the correctly calculated Patent Term Adjustment.

The revised Patent Term Adjustment was determined according to the grounds for adjustment under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) and was calculated according to the periods of adjustment under 37 C.F.R. § 1.703(a) and 37 C.F.R. § 1.703(b). Furthermore, the revised Patent Term Adjustment is established according to the recent decision by the U.S. Court for the District of Columbia in *Wyeth v. Dudas*, 580 F.Supp.2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008). A summary of the revised Patent Term Adjustment is below.

| | Relevant Dates | Period of Adjustment |
|--|---|---|
| Examination Delay under 37 C.F.R. § 1.702(a) | <p><i>37 C.F.R. § 1.703(a)(1)</i></p> <p>Filing date of patent application: <u>February 10, 2004</u></p> <p>Fourteen months after filing date of patent application: <u>April 10, 2005</u></p> <p>First Action mailed by USPTO: <u>September 19, 2006</u></p> <p><i>37 C.F.R. § 1.703(a)(2)</i></p> <p>Reply under 37 C.F.R. § 1.111 filed: <u>May 12, 2008</u></p> <p>Notice of Allowance mailed by USPTO: <u>September 26, 2008</u></p> | Difference for which patentee should receive credit: <u>+ 527 days</u> , plus <u>14 days</u> for Examination Delay in issuing the Notice of Allowance under 35 U.S.C. § 151, totaling <u>+ 541 days</u> |
| Examination Delay under 37 C.F.R. § 1.702(b) | <p><i>37 C.F.R. § 1.703(b)</i></p> <p>Filing date of patent application: <u>February 10, 2004</u></p> <p>Three years after filing date of patent application: <u>February 10, 2007</u></p> <p>Issue date of patent: <u>January 27, 2009</u></p> | Difference for which patentee should receive credit: <u>+ 717 days</u> , less <u>14 days</u> of overlap with Examination Delay under § 1.702(a), totaling <u>+ 703 days</u> |

U.S. Appl. No. 10/775,386
 Request for PTA Reconsideration

| | Relevant Dates | Period of Adjustment |
|--|--|--|
| Circumstances under 37 C.F.R. § 1.704(b) | <p>37 C.F.R. § 1.704(b)</p> <p>Request for a one-month Extension of Time -</p> <p>Restriction Requirement mailed by USPTO: <u>September 19, 2006</u></p> <p>Three-month due date: <u>December 19, 2006</u></p> <p>Response received by USPTO: <u>January 23, 2007</u></p> | <p>Difference for which §1.702 period of adjustment should be reduced: <u>-35 days</u></p> |
| Circumstances under 37 C.F.R. § 1.704(b) | <p>37 C.F.R. § 1.704(b)</p> <p>Request for a three-month Extension of Time -</p> <p>Office Action mailed by USPTO: <u>April 16, 2007</u></p> <p>Three-month due date: <u>July 16, 2007</u></p> <p>Response received by USPTO: <u>October 19, 2007</u></p> | <p>Difference for which §1.702 period of adjustment should be reduced: <u>-95 days</u></p> |
| Circumstances under 37 C.F.R. § 1.704(b) | <p>37 C.F.R. § 1.704(b)</p> <p>Request for a one-month Extension of Time -</p> <p>Office Action mailed by USPTO: <u>January 10, 2008</u></p> <p>Three-month due date: <u>April 10, 2008</u></p> <p>Response received by USPTO: <u>May 12, 2008</u></p> | <p>Difference for which §1.702 period of adjustment should be reduced: <u>-32 days</u></p> |
| Total PTA | | <u>1082 days</u> |

Pursuant to the decision rendered in *Wyeth v. Dudas*, a patentee is entitled to Patent Term Adjustment credit for examination delay under 37 C.F.R. § 1.702(a) in addition to any examination delay under 37 C.F.R. § 1.702(b), to the extent that the two periods of delay do not “occur on the same calendar day or days.” *Wyeth*, 580 F.Supp.2d at 140, 88 U.S.P.Q.2d at 1540. A copy of *Wyeth* is attached hereto as “Attachment A” for the Office’s convenience.

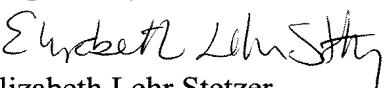
Accordingly, the patentee of the above-identified patent is entitled to a credit for the sum of 541 days under 37 C.F.R. § 1.702(a) and 717 days under 37 C.F.R. § 1.702(b), for a total of 1258 days, subject to a reduction of 162 days under 37 C.F.R. § 1.704. Additionally, there is a 14 day overlap between the delay periods under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b) and, pursuant the *Wyeth* decision, 14 additional days have been deducted from the total credit under 37 C.F.R. § 1.702. Thus, applicants respectfully submit the total Patent Term Adjustment is **1082 days**.

The above-identified patent is not subject to a terminal disclaimer.

This Request is timely filed under 37 C.F.R. § 1.705(d) as it is within two months of the date that the above-identified patent issued, i.e., January 27, 2009, and it does not raise an issue that was raised, or could have been raised, in an application for patent term adjustment under 37 C.F.R. § 1.705(b). The issue raised herein is a result of calculations which could not have been made until the issue date of the patent was known.

The Applicant respectfully requests revision of the Patent Term Adjustment as set forth above. The Commissioner is hereby authorized to charge Deposit Account No. 10-0435 in the amount of \$200.00 in payment of the reconsideration fee under 37 C.F.R. § 1.18(e). The Commissioner is also hereby authorized to charge any additional fees which may be required to Deposit Account No. 10-0435, with reference to our matter 3220-74469.

Respectfully submitted,


Elizabeth Lehr Stetzer
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Attorney for Applicants

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Indianapolis, Indiana 46204
317-231-7228
INDS02 ELEHR 1039348v1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :
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Plaintiffs, :
:
v. : Civil Action No. 07-1492 (JR)
:
JON W. DUDAS, Under Secretary of :
Commerce for Intellectual :
Property and Director of U.S. :
Patent and Trademark Office, :
:
Defendant. :
:

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

ATTACHMENT A

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b) (1) (A), the “[g]uarantee of prompt Patent and Trademark Office response.” It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b) (1) (A) (i)-(iv). Periods of delay that fit under this provision are called “A delays” or “A periods.” The second provision is the “[g]uarantee of no more than 3-year application pendency.” Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ See 35 U.S.C. § 154(b) (1) (B). The period that begins after the three-year window has closed is referred to as the “B delay” or the “B period.” (“C delays,” delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b) (1) (B) (i)-(iii), as are periods attributable to the applicant’s own delay. See 35 U.S.C. § 154(b) (2) (C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b) (2) (A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b) (3) (A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b) (2) (A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH, et al., :
:
Plaintiffs, :
:
v. : Civil Action No. 07-1492 (JR)
:
JON W. DUDAS, Under Secretary of :
Commerce for Intellectual :
Property and Director of U.S. :
Patent and Trademark Office, :
:
Defendant. :
:

ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON
United States District Judge